DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 23, 2014

Total Joint Orthopedics, Incorporated
Mr. Chris Weaber
Manufacturing Development Engineer
1567 East Stratford Avenue
Salt Lake City, Utah 84106

Re: K143407
Trade/Device Name: Klassic HD™ Hip System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, LPH, MBL
Dated: November 26, 2014
Received: November 28, 2014

Dear Mr. Weaber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K143407 (page 1/1)

Device Name: Klassic HD™ Hip System

The Klassic HD™ Hip System is intended for prosthetic replacement without bone cement in treatment of the following:

- Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis, osteoarthritis, ankylosis, protrusio acetabuli and painful hip dysplasia.
- Patient conditions of inflammatory joint disease (IJD): rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- Revision of a previously failed hip arthroplasty.
- Patients who require a total hip replacement.

Prescription Use ___√____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5. 510(k) Summary

Contact:	Mr. Chris Weaber Manufacturing Development Engineer
Prepared By:	Musculoskeletal Clinical Regulatory Advisers, LLC 1331 H Street, NW, 12th Floor Washington, DC 20005 Phone: 202.552-5800 Fax: 202.552.5798
Date Prepared:	November 26, 2014
Device Trade Name:	Klassic HD™ Hip System
Manufacturer:	Total Joint Orthopedics, Inc. 1567 E. Stratford Avenue Salt Lake City, UT 84106 Phone: 801.486.6070 Fax: 801.486.6117
Classifications:	21 CFR 888.3353 - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis 21 CFR 888.3358 - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis Class II
Product Codes:	LZO, LPH, MBL

Reason for Special 510(k) Submission:
The purpose of this Special 510(k) is to add ceramic femoral heads to the Klassic HD™ Hip System. There have been no changes to the intended use of the device or its fundamental scientific technology.

Indications For Use:
The Klassic HD™ Hip System is intended for prosthetic replacement without bone cement in treatment of the following:

- Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis, osteoarthritis, ankylosis, protrusio acetabuli and painful hip dysplasia.
- Patient conditions of inflammatory joint disease (IJD): rheumatoid arthritis.

- Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- Revision of a previously failed hip arthroplasty.
- Patients who require a total hip replacement.

Device Description:
The Klassic HD™ Hip System employs a prosthesis designed to help surgeons restore hip joint biomechanics intraoperatively by independently addressing the size of the femur and acetabulum, leg length, offset and version. The Klassic HD™ Hip System can be mated with metal (CoCrMo) or ceramic femoral heads and UHMWPE acetabular components.

Predicate Devices:
The modified Klassic HD™ Hip System is substantially equivalent to the predicate Klassic HD™ Hip System (K100445) with respect to indications, design, and function.

Substantial Equivalence:
The company performed burst strength testing, fatigue testing, post-fatigue burst strength testing and pull-off testing of the ceramic femoral heads. The test results demonstrate that the pre-determined acceptance criteria identified in the Design Control Activities Summary were met.

Conclusion
The Klassic HD™ Hip System when mated with a ceramic femoral head is substantially equivalent to previously cleared devices with respect to its indications for use, design, and function.